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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
OROPEZA, FRANCES P	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/927,225	ERICKSON ET AL.	
	Examiner	Art Unit	
	Frances P. Oropeza	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/27/04 (RCE and Amendment)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13 and 15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Request for Continued Examination

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. The Applicant's submission filed on 4/27/04 has been entered.

Restriction

2. The Applicant traversed the restriction requirement arguing the Examiner failed to provide a proper basis to support the present restriction requirement that Claim 14 is directed to an invention that is independent or distinct from the invention as originally claimed.

The Examiner offers the following clarification. Newly submitted claim 14 comprises "a first electrode and a second electrode". The originally elected independent claims, 1, 4, 6, 8 and 11 comprise "a plurality of electrodes". The "plurality of electrodes" according to paragraph 0008 of the specification is defined as "a plurality of electrodes (for example, two, four, eight or sixteen)". Accordingly, contrary to the arguments provided by the Applicant, "a first electrode and a second electrode" is not the same limitation as "a plurality of electrodes (for example, two, four, eight or sixteen)". Claim 14 contains a limitation, "a first electrode and a second electrode", not found in the original claims 1, 4, 6, 8 and 11, hence restriction requirement is deemed proper and stands.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 1-3, 6-13 and 15-18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for "wherein the greatest transverse dimension of the body of the lead is less that a corresponding interior dimension of the percutaneous introduction structure", does not reasonably provide enablement for "wherein the greatest transverse dimension of the lead is less that a corresponding interior dimension of the percutaneous introduction structure". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. The Examiner references paragraph 0015 of the specification, which appears to provide the basis for this limitation, and notes the limitation focuses on the body of the lead and not just the lead. This issue is associated with claims 1, 6, 8, 11 and 16.

Claim Rejections - 35 USC § 102

5. Claims 1-13 and 15-19 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. (US 6161047). King et al. disclose a stimulation lead (figures 1, 2A, 10A and 10B; col. 3 @ 51-57 and 60-67; col. 6 @ 54-62; col. 7 @ 20-32; col. 10 @ 50-55). Multiple spans can be included, hence providing a waisted regions between plurality of electrodes (col. 7 @ 14-15).

As to providing a lead where the greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure, in the instant

specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is provided to enable percutaneous implantation. King et al. teach a compacted lead position (figure 10A) where the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure to enable implantation (col. 10 @ 50-55).

As to the lead body has a varying transverse dimension enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead, King et al. teach the lead body has a varying transverse dimension, transverse by virtue of the spans both in the compacted position (figure 10A) and natural position (figure 10B), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead, providing more rigidity in the plane at the points of the spans and less rigidity in the plane between the spans. King et al. teach the lead body is steerable enabling easy insertion using a catheter/ needle / insertion tool (col. 3 @ 51-57). When the lead body does not have adequate structural support for steering, King et al. teach lead deployment using a stylet (25) (col. 7 @ 20-32).

The Applicant's arguments filed 4/27/04 have been fully considered, but they are not convincing.

In response to the Applicant's argument that the reference fails to show a certain feature of the Applicant's invention, it is noted that the feature upon which the Applicant relies (i.e. dimension of the lead in an unexpanded state) is not recited or distinguished in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the

specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As to claim 4, the Applicant argues King et al. fail to disclose that the lead body has a varying transverse dimension that enable flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. The Examiner disagrees. As to figures 2A- 2E, 10A and 10B, the lead is steerable as indicated by the use of a stylet (col. 7 @ 21-27) and the method of insertion as indicated in figure 1 where flexibility of the lead is required so the lead can bend according to the path defined by the Tuohy needle. The lead of figures 2A-2E is rotated during insertion such that the varying transverse dimension of the lead body, the lead at the point of the spans, is positioned in a plane substantially parallel to the principal surfaces of the body of the lead and provides flexibility to enable insertion (col. 3 @ 60 – col. 4@ 11). The lead of figures 10A and 10B provides the spans remain parallel to the lead during insertion such that the varying transverse dimension of the lead body, the lead at the point of the spans, is positioned in a plane substantially parallel to the principal surfaces of the body of the lead and provides flexibility to enable insertion (col. 10 @ 53-57).

6. Claims 1-7 are rejected under 35 U.S.C. 102(e) as being anticipated by Kuzma et al. (US 6522932). Kuzma et al. disclose a paddle-type electrode for spinal stimulation (figures 3, 7A, 7C and 11A; abstract; col. 2 @ 8-22; col. 6 @ 42-46 and 63-66).

As to providing a lead where a greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure, in the instant specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is

provided to enable percutaneous implantation. Kuzma et al. teach a lead in an insertion structure (50) (figure 7C) where on insertion the greatest transverse dimension of the lead body is less than a corresponding interior dimension of the percutaneous introduction structure (col. 6 @ 42-46).

As to the lead body has a varying transverse dimension enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead, Kuzma et al. teach the lead body has a varying transverse dimension, transverse by virtue of the columns of electrodes (figure 7A - 42a, 42b), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead. Kuzma et al. teach the lead body is steerable enabling deployment using an insertion tool (50) and proper material of construction for the lead body as the lead moves into position in the spinal cavity (col. 6 @ 59-62). When the lead body configuration does not have adequate structural support, Kuzma et al. teach lead deployment using a stylet (54) (col. 6 @ 63-66).

The Applicant's arguments filed 4/27/04 have been fully considered, but they are not convincing.

In response to the Applicant's argument that the reference fails to show a certain feature of the Applicant's invention, it is noted that the feature upon which the Applicant relies (i.e. dimension of the lead in an unexpanded state) is not recited or distinguished in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

As to claim 4, the Applicant argues Kuzma et al. fail to disclose that the lead body has a varying transverse dimension that enable flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. The Examiner disagrees. The lead is steerable as indicated by the use of a stylet (col. 6 @ 63-66) and the lead is based on a flexibility substrate/ webbing (col. 1 @ 56-58; col. 2 @ 8-22; col. 5 @ 56-63). The lead of figures 7A and 7C is inserted such that the varying transverse dimension of the lead body, the lead at the point of the columns, is positioned in a plane substantially parallel to the principal surfaces of the body of the lead and provides flexibility to enable insertion (figure 7C).

Claim Rejections - 35 USC § 102 and 103

7. Claims 1-13 and 15-19 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Errico et al. (US 6175769) in view of Kohnen et al. (US 6249707).

Errico et al. disclose a spinal cord electrode assembly (figures 1 and 3; col. 2 @ 56-63; col. 3 @ 41-52; col. 4 @ 46-50). Errico et al. disclose the art of spinal lead implantation has progressed from an invasive procedure to use of percutaneous positioning (col. 1 @ 22-34). When using percutaneous positioning, Errico et al. identified the lack of lead stabilization as an issue (col. 1 @ 40-46), and disclosed a method to reduce migration of the lead/ electrodes when using percutaneous positioning (col. 2 @ 9-12), hence the lead is read to be implanted percutaneously. It is accepted that percutaneous positioning includes passing the lead through an insertion structure. The distal terminal pad (103) configured such that the wasted regions are

positioned between two of the plurality of electrodes (figure 1), the electrodes extending the length of the pad.

In the alternative, it is well known in the spinal stimulation art to use a percutaneous introduction structure and percutaneous lead positioning to implant a spinal stimulation lead non-surgically. Kohnen et al. disclose non-surgical spinal lead implantation using an apparatus, a percutaneous introduction structure (figure 3 – 15), and method for percutaneously implanting the lead (col. 4 @ 64 – col. 5 @ 18). It would have been obvious to one having ordinary skill in the art at the time of the invention to have used percutaneous lead positioning and a percutaneous introduction structure in the Errico et al. system in order to provide a minimally invasive means for lead insertion that requires only local anesthetics and minimizes the recovery issues/ complication typically associated a surgical spinal lead implantation procedure (Errico et al. – col. 1 @ 28-29 and 32-34; Kohnen et al. - figure 3; col. 1 @ 54 – col. 2 @ 16; col. 4 @ 64 – col. 5 @ 18).

As to providing a lead where the greatest transverse dimension of the lead is less than a corresponding interior dimension of the percutaneous introduction structure, in the instant specification, paragraphs 0015 and 0038, the narrow transverse dimension of the lead body is provided to enable percutaneous implantation. Errico et al. focus the invention to optimize lead stabilization following percutaneous positioning (col. 1 @ 22-34; col. 2 @ 9-12, 47-50), percutaneous positioning being accepted to include passing the lead through an insertion structure, hence requiring that the greatest transverse dimension of the body is less than a corresponding interior dimension of the percutaneous introduction structure (Errico et al. – figures 1, 2; Kohnen et al. - col. 4 @ 64 – col. 5 @ 3).

As to the lead having a varying transverse dimension that enables flexibility in a plane substantially parallel to the principle surface of the body of the lead and fails to provide steerablilty of the lead, Errico et al. teach the lead body has a varying transverse dimension, transverse by virtue of the laterally extending portions (figures 1,2 - 101), hence enabling flexibility in a plane substantially parallel to the principle surface of the body of the lead. Errico et al. teach the lead body is steerable based on proper material of construction for the lead body (col. 1 @ 55-60). When the lead body configuration does not have adequate structural support for steerablity, Errico et al. teach lead deployment using a rigid wire/ stylet (col. 4 @ 46-50).

The Applicant's arguments filed 4/27/04 have been fully considered, but they are not convincing.

The Applicant argues Errico et al. does not teach percutaneous lead insertion. The Examiner disagrees. In addition to the references cited in the rejection of record, Errico et al. teach the use of a rigid wire backbone to enable proper positioning of the lead (col. 2 @ 47-50). If the lead were surgically implanted as argued by the Applicant, the use of a rigid wire backbone would be unnecessary. In addition the Applicant cites col. 3 @ 41-44 to prove that the lead is not percutaneously implanted. The Examiner reads the percutaneous lead insertion procedure as a spinal surgery procedure conducted by a surgeon. The Applicant further argues that because the lead is not percutaneously inserted, Errico et al. fails to disclose a lead body wherein a greatest transverse dimension of the lead is less than a corresponding interior dimension of a percutaneous introduction structure. When the lead is percutaneously introduced (col. 1 @ 40-46; col. 2 @ 9-12, 47-50), the extending portions (figure 1 – 101) and the lead are less than a

corresponding interior dimension of a percutaneous introduction structure, hence enabling lead insertion.

In response to the Applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). In the alternative, Kohnen et al. is combined with Errico et al.. Kohnen et al. disclose non-surgical spinal lead implantation using an apparatus, a percutaneous introduction structure (figure 3 – 15), and method for percutaneously implanting the lead (col. 4 @ 64 – col. 5 @ 18), hence Errico et al and Kohnen et al. teach percutaneous lead insertion. The Applicant further argues that because the lead is not percutaneously inserted, Errico et al. fails to disclose a lead body wherein a greatest transverse dimension of the lead is less than a corresponding interior dimension of a percutaneous introduction structure. When the lead is percutaneously introduced (col. 1 @ 40-46; col. 2 @ 9-12, 47-50), the extending portions (figure 1 – 101) and the lead are less than a corresponding interior dimension of a percutaneous introduction structure, hence enabling lead insertion.

As to claim 4, the Applicant argues Errico et al. fail to disclose that the lead body has a varying transverse dimension that enable flexibility in a plane substantially parallel to the principal surfaces of the body of the lead and provides steerability of the lead. The Examiner disagrees. The lead is steerable as indicated by the use of a rigid wire/ stylet (col. 2 @ 46-50) and the lead is flexible (col. 2 @ 41-44; col. 4 @ 42-45; col. 6 @ 9-10). The lead of figures 1 and 2 is inserted such that the varying transverse dimension of the lead body, the lead at the point of the columns, is positioned in a plane substantially parallel to the principal surfaces of the body

of the lead (figure 3) and provides flexibility to enable insertion (col. 2 @ 41-44; col. 4 @ 42-45; col. 6 @ 9-10).

Statutory Basis

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355. The Examiner can normally be reached on Monday – Friday from 9 a.m. to 5:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
7/22/04

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